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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,223	10/31/2003	Warren L. Starkebaum	P-11296.00	1509
27581	7590	06/21/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/698,223	Applicant(s) STARKEBAUM ET AL.	
	Examiner Alex B. Toy	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 and 18-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on April 10, 2006. The objection to claim 3 is withdrawn in view of the appropriate amendment. All previous prior art rejections are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards (U.S. Pat. No. 6,405,732 B1) in view of Edwards (U.S. Pat. No. 6,254,598 B1).

Regarding claim 1, Edwards ('732) discloses the step of:
ablating fundal tissue within a stomach with an ablation probe sized to fit the stomach to inhibit the production of acid by the fundal tissue.

Since the device of Edwards ('732) ablates the fundus (col. 24, ln. 54-56, col. 26, ln. 1-10, and col. 28, ln. 1-4), it must inherently inhibit the production of acid by the fundal tissue.

The claim differs from Edwards ('732) in calling for the steps of:
determining a first acid level of a patient with a hyperacid condition;
determining a second acid level of the patient following a period of time after ablation.

Edwards ('598), however, teaches a pH monitoring catheter (col. 5, ln. 65-67) that inherently determines a first and second acid level as claimed in order to monitor pH levels of a patient with a hyperacid condition. Since the device of Edwards ('732) is also for treating a patient with a hyperacid condition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a pH monitoring catheter in the device of Edwards ('732) in view of the teaching of Edwards ('598) in order to monitor pH levels of a patient with a hyperacid condition.

Therefore, since the device of Edwards ('732) in view of Edwards ('598) performs the steps of claim 1, the Office maintains that the combination inherently discloses a method for reducing stomach acid secretion.

Regarding claim 2, Edwards ('732) discloses the method of claim 1 in view of Edwards ('598), wherein determining the first acid level comprises monitoring acid reflux levels with an esophageal pH monitor. Since Edwards ('598) discloses a pH monitor that is used in the esophagus (col. 5, ln. 65-67), it is inherently capable of monitoring acid reflux levels to determine a first acid level.

Regarding claim 3, Edwards ('732) discloses the method of claim 1 in view of Edwards ('598), wherein the first and second acid levels are first and second esophageal acid levels. Since Edwards ('598) discloses a pH monitor that is used in the esophagus (col. 5, ln. 65-67), it inherently measures esophageal acid levels.

Regarding claim 4, Edwards ('732) discloses the method of claim 1 in view of Edwards ('598), wherein inhibiting the production of stomach acid comprises reducing an amount of acid refluxed into an esophagus of the patient. Since ablation of the fundus inherently inhibits the production of stomach acid, it would inherently reduce the amount of acid that is available to be refluxed into an esophagus of the patient.

Regarding claim 5, Edwards ('732) discloses the method of claim 1 in view of Edwards ('598). The claim differs from Edwards ('732) in view of Edwards ('598) in calling for the period of time after ablation to comprise one week. Edwards ('598) includes a pH monitoring catheter (col. 5, ln. 65-67) but is silent with respect to any time periods. At the time the invention was made, however, it would have been obvious to one of ordinary skill in the art to measure pH at any desirable time after the ablation procedure.

Regarding claim 6, Edwards ('732) discloses the method of claim 1 in view of Edwards ('598), wherein ablating tissue comprises ablating at least a portion of a mucosal lining of the stomach. Since the device of Edwards ('732) ablates the fundus, it must inherently ablate at least a portion of a mucosal lining of the stomach.

Regarding claim 7, Edwards ('732) discloses the method of claim 1 in view of Edwards ('598), wherein ablating tissue comprises ablating cells that produce stomach acid. Since the device of Edwards ('732) ablates the fundus, it must inherently ablate cells that produce stomach acid.

Regarding claim 8, Edwards ('732) discloses the method of claim 1 in view of Edwards ('598), wherein ablating tissue comprises:

inserting an ablation probe to the stomach via an esophagus of the patient (Fig. 2a);

moving the ablation probe to a position proximate to a mucosal lining of the stomach; and

activating the ablation probe to ablate at least a portion of the mucosal lining.

Again, since the device of Edwards ('732) ablates the fundus, it must inherently ablate at least a portion of the mucosal lining.

Regarding claim 9, Edwards ('732) discloses the method of claims 1 and 8 in view of Edwards ('598), where the ablation probe comprises at least one of a radio frequency, laser, ultrasonic, microwave, thermal, chemical, mechanical, and cryogenic ablation probe (col. 26, ln. 1-13 and col. 28, ln. 1-4).

Regarding claim 10, Edwards ('732) discloses the method of claims 1 and 8 in view of Edwards ('598), wherein activating the ablation probe comprises delivering energy to the mucosal lining of the stomach via the ablation probe (see the rejections of claims 8 and 9).

Regarding claim 11, Edwards ('732) discloses the method of claims 1 and 8 in view of Edwards ('598), wherein the ablation probe comprises at least one electrode and wherein activating the ablation probe comprises delivering electrical current to the mucosal lining of the stomach via the electrode (see the rejections of claims 8 and 9).

Regarding claim 16, Edwards ('732) discloses the method of claims 1 and 8 in view of Edwards ('598), wherein the catheter of Edwards ('732) comprises an endoscope (col. 14, ln. 52-54).

Regarding claim 17, Edwards ('732) discloses the method of claim 1 in view of Edwards ('598), further comprising ablating additional stomach tissue based on a comparison of the second esophageal acid level to the first esophageal level. Since the device of Edwards ('598) includes a pH monitoring catheter (col. 5, ln. 65-67), it inherently ablates additional stomach tissue based on a comparison of the second esophageal acid level to the first esophageal level.

Response to Arguments

Applicant's arguments with respect to claims 1-11 and 16-17 have been considered but are moot in view of the new ground(s) of rejection. It is also noted that applicant did not present arguments with regards to Edwards ('598) anticipating or

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rendering obvious the determining of acid levels at different times or ablating stomach tissue based on an acid level comparison.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 20020128636 A1 US-PGPUB Chin, Sing Fatt et al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
6/12/06

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER